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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,790	ROSENBLOOM, RICHARD A.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/19/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-20 and 38-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-20 and 38-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 12/19/2005. Claims 8, 21-37, 42 have been cancelled. Claims 1, 5-6 have been amended. Claims 1-7, 9-20, 38-41 are pending and are examined herein. Applicant's arguments have been fully considered but found persuasive to withdraw the 35 USC 112-2nd rejection only, while the provisional double patenting and 103(a) rejections are maintained for reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-9, and 12- 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/288,761 for same reasons of record stated in the Office Action dated October 20, 2004.

Although the conflicting claims are not identical, they are not patentably distinct

from each other because the copending application is drawn to the same method of the treatment comprising the same active agents as the claims of the instant application. Thus, these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 1, 4-9, and 12- 20 are seen to be obvious over the claims 1-40 of copending Application No. 10/288,761 .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-9, and 12- 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/279,315 for same reasons of record stated in the Office Action dated October 20, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is drawn to a method for the reduction or treatment of reactive and inflammatory dermatoses comprising the same active agents as the claims of the instant application. One of ordinary skill in the art would recognize that radiation injury in a patient would be reactive and inflammatory dermatoses. Thus, these methods between in the copending application and in the instant application are seen to substantially overlap.

Thus, the instant claims 1, 4-9, and 12- 20 are seen to be obvious over the claims 1-25 of copending Application No. 10/279,315.

This is a provisional obviousness-type double patenting rejection because the

conflicting claims have not in fact been patented.

Applicant requests deferral of these provisional obviousness-type double patenting rejections until such time as notice of allowance in said co-pending applications are received is noted. Nonetheless, for the reasons of record, said rejections are maintained at this point.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 7, 9-20, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett (US 6,051,602, PTO-892), and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record).

Kita discloses that vitamin D including vitamin D3 (cholecalciferol), is useful in a

dermatological composition for the protection and treatment of the skin and scalp from harmful UV radiation. See 6,162,801, abstract, col. 1, lines 22-24 and 51-67, col. 4, lines 13-16, and col. 8, lines 51 to col. 9.

Bissett (US 6,051,602) discloses that the instant one or more flavonoids (also known as polyphenols and are known to be obtained from green teas extracts, including catechin, epicatechin, and rutin compounds) are useful in a method of reduction or treatment skin conditions in human resulted from environmental damage or extrinsic factors such as UV radiation, pollution, wind, heat or IR, low humidity, harsh surfactants, by topically applying a composition comprising one or more flavonoids, a pharmaceutically acceptable carrier broadly (e.g., PPG), and other active agents such as anti-inflammatorv aoents and anti-oxidants such as vitamin A (retinol or retinyl derivatives) and C (ascorbic acid), with conventional skin care product additives such as kernel oil, panthenol, to human skin. See in Bissett, the abstract, col. 1, col. 2, lines 14-48, col. 3, lines 13-36 and 53-55, col. 4, lines 13-16, col. 4, lines 65 to col. 5, line 49, col. 6, lines1-55, col. 7, lines 1-10, Example 1 and 3 at col. 9-10, and claims 1-11. Bissett discloses the effective amounts of one or more flavonoid compounds, about 0.01-20%, more preferably, about 0.1-10%, and most preferably about 0.5-5%, within the instant claim (see col. 5, lines 60-64).

Darr et al. discloses that vitamin C such as ascorbic acid or vitamin E is useful in a composition to be administered orally or topically in the treatment of the protection of UV radiation-induced damage. See Summary and page 247.

The prior art does not expressly disclose the employment of the combination of

vitamin D3 and ascorbyl palmitate and flavonoid / flavonoid derivatives, and ginseng in a composition to be administered in a method for the treatment or reduction of radiation injury. The prior art does not expressly disclose that the particular radiation is proton, fluoroscopic, alpha, beta, or gamma radiation.

Shimoi et al. discloses that flavonoid / flavonoid derivatives from plant or tea are antioxidants and have radioprotective effects. See abstract.

Kim et al. discloses that ginseng is known to be useful in the protection of radiation injury. See col. 1, lines 21-27.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the combination of vitamin D3 and ascorbyl palmitate and flavonoid / flavonoid derivatives, and ginseng in a composition to be administered in a method for the treatment or reduction of radiation injury.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the combination of vitamin D3 and ascorbyl palmitate in a composition to be administered in a method for the treatment or reduction of radiation injury since vitamin D such as vitamin D3 is known to be useful for the protection and treatment of the skin and scalp from harmful UV radiation. Antioxidants such as vitamin C (ascorbic acid) is known to be useful in the treatment and the protection of UV radiation-induced damage. Moreover, ascorbyl palmitate is a known vitamin C (an ester of ascorbic acid). Therefore, one of ordinary skill in the art would have reasonably expected that combining vitamin D3 and ascorbyl palmitate known useful for the same purpose, i.e., treating radiation damage, in a composition to be would improve the

therapeutic effect in treating radiation injury.

Further, both flavonoid / flavonoid derivatives and ginseng are known antioxidants and also known to be useful in the protection of radiation injury. Therefore, one of ordinary skill in the art would have reasonably expected that further adding both flavonoid / flavonoid derivatives and ginseng to the composition herein known useful for the same purpose, in a composition to be administered would provide additive effects for the therapeutic treatment in radiation injury.

Furthermore, one of ordinary skill in the art would have reasonably expected that the combination herein would have same or substantially same beneficial therapeutic effects in proton, fluoroscopic, alpha, beta, or gamma radiation, as in UV radiation-induced damage.

Since all active composition components herein are known to useful to treat radiation injury, it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 5-6 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over KITA, K (WO 9718817, equivalent to 6,162,801), and Bissett (US 6,051,602, PTO-892), and Darr et al. (of record) in view of Shimoi et al. (of record) and Kim et al. (5,776,460, of record), further in view of Ishida et al. (US 5141741, of record) or Nguyen

et al. (US 5650137, of record).

The same disclosures of KITA, K, and Bissett et al. and Darr et al. in view of Shimoi et al. and Kim et al. have been discussed in the 103(a) rejection set forth above.

The prior art does not expressly disclose the employment of the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition to be administered in a method for the treatment or reduction of radiation injury. Ishida et al. discloses that alpha-lipoic acid and vitamin A, B, C, D, E, F, K, P, U are known to be useful in the protection of UV radiation or anti-sunburn in human skin. See abstract, col.5 lines 65-68.

Nguyen et al. discloses that superoxide dismutase or the porphyrins such as chlorophyllin, alone or in combination are antioxidants and have protective effects to human skin including against UV radiation. See abstract, col. 1, col. 2, lines 20-31, col.3 lines 40-66, claims 1-11.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition to be administered in a method for the treatment or reduction of radiation injury.

One having ordinary skill in the ad at the time the invention was made would have been motivated to employ the particular antioxidant, alpha-lipoic acid or chlorophyllin or superoxide dismutase in a composition to be administered in a method for the treatment or reduction of radiation injury, since alpha-lipoic acid or chlorophyllin or superoxide dismutase, alone or their combination is well known to be useful for the

protection and treatment of the skin and scalp from harmful UV radiation, as those known antioxidants taught by the cited prior art.

Therefore, one of ordinary skill in the art would have reasonably expected that alpha-lipoic acid or chlorophyllin or superoxide dismutase, alone or their combination would have the same usefulness and provide additive effects for the therapeutic treatment in radiation injury. See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).

Response to Arguments

Applicant argues that the cited references do not contain every element of a case of obviousness, since the use of D vitamins are not used for treating radiation injury. Examiner respectfully disagrees as Shimoi et al. teach of radioprotective effects and Kim et al. teach of protection of radiation injury, while Kita et al. teach vitamin D3. The motivation is the same of that on record.

Applicant argues that there is no motivation because the Examiner's position is apparently inconsistent, stemming from the statement made on April 30, 2004 stating, "that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity." This statement is taken out of context and does not apply to the arguments in regard to the instant 35 USC 103(a) rejection. This statement was made in a 35 USC 112-1st rejection concerning a scope of enablement.

Applicant argues that the declaration is sufficient because the prior art presented by the Examiner presents no evidence that the results would not apply and that none of the prior art even relates to the same purpose as the present invention. Examiner

respectfully disagrees. Again, there is no clear and convincing evidence in the declaration for supporting nonobviousness or unexpected results. There is no side-by-side comparison with the closest prior art. Furthermore, the declaration is not commensurate with the scope of the subject matter claimed.

Finally, applicant argues that UV radiation has different wavelengths than those that are being claimed and that Kita et al. discloses oral digestion of vitamin D3, thus rendering radiation protection impossible. Examiner respectfully disagrees. Firstly, Shimoi et al. and Kim et al. both disclose protection from radiation injury, which effectively encompasses the species claimed. There is sufficient overlap between UV radiation and those that are being claimed to render it obvious. Secondly, Kita et al. discloses a dermatological composition for the protection and treatment of the skin and scalp.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SHENGJUN WANG
PRIMARY EXAMINER